105 CMR: Department of Public Health

105 CMR 665.000: Testing and Reporting of Constituents of Cigarette Smoke

665.001: Purpose

The purpose of these regulations is to establish procedures for cigarette manufacturers to test for and report the amounts of certain specified constituents which may be found in cigarette smoke and which are known or believed to be the cause of morbidity and mortality in the Commonwealth.

665.002: Authority

These regulations are adopted pursuant to M.G.L. c. 111, ss. 5 and 6.

665.003: Definitions

As used in 105 CMR 665.000 et seq., the following terms shall have the following meanings, unless the context clearly requires otherwise:

Manufacturer means any person or entity, including any repacker or relabeler, that manufactures, fabricates, assembles, processes or labels a finished cigarette. The term does not include any person or entity only distributing finished cigarettes.

Market share means United States market share as of the effective date of this regulation, and for subsequent calendar years means United States market share as of December 31 of the preceding calendar year.

Smoke constituents means those components of mainstream smoke and sidestream smoke, identified in sections 105 CMR 665.200 and 665.202, which are present in the mainstream and sidestream smoke of a cigarette when tested in accordance with these regulations.

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Smoke constituent yield rating means the amount of a smoke constituent contained in the smoke of a particular brand, sub-brand or generic unbranded cigarette product, as tested and reported in accordance with the requirements of these regulations.

Smoke metabolites means the metabolic by-products of smoke constituents inhaled into the body.

665.004: Regulatory Basis

Pursuant to M.G.L. c. 111, s. 6, and solely for the purpose of these regulations, the Department defines the term "diseases dangerous to the public health" to include lung, mouth and nasal sinus cancer, heart disease, stroke, pneumonia, and bronchitis.

665.100: Smoke Constituent Reporting

(A) By March 1, 2001, and by every March 1 thereafter, the Department will select a representative sample of 35 cigarette brands, sub-brands, or generic unbranded cigarettes sold in the Commonwealth for testing and reporting of smoke constituents in accordance with these regulations. Manufacturers will be notified promptly of the selections made by the Department. Beginning December 1, 2001, and each December 1 thereafter, for each of the 35 cigarette brands, sub-brands, or generic unbranded cigarettes selected by the Department, a manufacturer shall submit an annual report to the Department for each selected brand which lists a yield rating for each of the mainstream and sidestream smoke constituents identified in sections 105 CMR 665.200 and 665.202, in accordance with the requirements of these regulations.

(B) Smoke constituents shall be reported under 105 CMR 665.100(A) on the basis of the average yield per cigarette for each brand selected. The yield ratings for smoke constituents shall be reported on the form specified in 105 CMR 665.300. In addition, such report shall be submitted electronically to the Department in accordance with the technical specifications of the Department. All raw data generated by testing in accordance with these regulations should be submitted as part of this report.

(C) By March 1, 2001, and by every March 1 thereafter, the Department will select a representative sample of 15 brands, sub-brands, or generic unbranded cigarettes, which shall correspond to the brands selected in accordance with 105 CMR 660.103 (B)(3) (human nicotine intake). Manufacturers will be promptly notified of the selections made by the Department. For this sample of 15 brands, sub-brands, or generic unbranded cigarettes, manufacturers shall test for and report mainstream smoke metabolites in accordance with 105 CMR 665.201. The report shall be submitted electronically to the Department in accordance with the technical specifications of the Department. All raw data generated by testing in accordance with these regulations shall be submitted as part of this report.

(D) A multiplier equation shall be developed by manufacturers annually, based on the reported results of brands tested in accordance with 665.100 (A) and (B), correlating

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mainstream and sidestream smoke constituent data to tar, nicotine, and CO levels reported to the Department pursuant to section 660.102.

665.101: Smoke Constituent Testing

All testing and analysis for the purpose of the reports submitted under 105 CMR 665.100 (A) through (C) shall be carried out in accordance with the applicable testing methods set forth in 105 CMR 660.500, and in accordance with Procedures for the Testing of Mainstream and Sidestream Smoke Constituents and Mainstream Smoke Metabolites, published by the Massachusetts Department of Public Health, or a comparable method approved by the Department.

665.200: Testing for Mainstream Smoke Constituents

In accordance with the requirements of 105 CMR 665.101, manufacturers shall test mainstream smoke, that is, the smoke directly inhaled by a smoker from a lit cigarette, of cigarettes identified pursuant to section 665.100 (A) for the following smoke constituents:

A. ammonia
B. aromatic amines (1-aminonapthalene, 2-aminonapthalene, 3-aminobiphenyl and 4-aminobiphenyl)
C. benzo[a]pyrene
D. volatile carbonyls (formaldehyde, acetaldehyde, acetone, acrolein, propionaldehyde, crotonaldehyde, methyl ethyl ketone and butyraldehyde)
E. hydrogen cyanide
F. mercury
G. toxic trace metals (lead, cadmium, and arsenic)
H. nitric oxides (NO and NO_2)
I. tobacco specific nitrosamines (N-nitrosonornicotine (NNN), 4-(N-nitrosomethylamino)- 1-(3-pyridyl)-1 butanone (NNK), N-nitrosoanatabine (NAT) and N-nitrosoanabasine (NAB))
J. selected basic semi-volatiles (pyridine and quinoline)
K. phenolic compounds (hydroquinone, catechol, phenol, m+p-cresol, and o-cresol)
L. tar and carbon monoxide
M. selected volatiles (1, 3-butadiene, isoprene, acrylonitrile, benzene, toluene, styrene)

665.201: Mainstream Smoke Metabolites

In accordance with the requirements of 105 CMR 665.101, manufacturers shall test cigarette products identified in section 665.100 (C) for mainstream smoke metabolites. The same set of sixty smokers (30 male, 30 female) identified in accordance with 660.500 (B) shall be tested by the manufacturer for each brand (for a total of 900 smokers). They shall have smoked for at least five years, currently smoke at least 15 cigarettes per day and have smoked the brand to be tested, or a brand with equivalent levels of tar and nicotine, for at least three months. Mainstream smoke metabolites will

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be determined by collecting a urine sample and testing for levels of 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL) and its glucuronide, which are metabolites of 4- (methylnitrosamino)-1-(3-pyridyl)-1-buranone (NNK), in accordance with the method described in Hecht SS, Carmella SG, Murphy SE, Akerkar S, Brunnemann KD, and Hoffmann D, "A Tobacco-Specific Lung Carcinogen in the Urine of Men Exposed to Cigarette Smoke", *New England Journal of Medicine* 1993, 329(21):1543-6, or comparable method approved by the Department. Levels of the urinary benzene metabolite, trans,trans-muconic acid (t,t- MA), shall be tested in accordance with the method described in Melikian AA, Prahalad AK, Hoffmann D, "Urinary Trans,trans-muconic Acid as an Indicator of Exposure to Benzene in Cigarette Smokers", *Cancer Epidemiol. Biomarkers Prev.* 1993, 2(1):47-51, or comparable method approved by the Department. Reporting for each brand shall include background smoker data collected in accordance with 105 CMR 660.500 (F). Research on human intake of nicotine shall be conducted in accordance with federal regulations governing protection of human subjects, Title 45 of the Code of Federal Regulations, Part 46.

665. 202: Sidestream Smoke Constituents

In accordance with the requirements of 105 CMR 665.101, manufacturers shall test cigarettes identified pursuant to section 665.100 (B) for the sidestream smoke of a cigarette, that is, the smoke that is emitted from the burning end of a cigarette between puffs, for the following smoke constituents:

A. ammonia
B. aromatic amines (1-aminonapthalene, 2-aminonapthalene, 3-aminobiphenyl and 4-aminobiphenyl)
C. benzo[a]pyrene
D. volatile carbonyls (formaldehyde, acetaldehyde, acetone, acrolein, propionaldehyde, crotonaldehyde, methyl ethyl ketone and butyraldehyde)
E. hydrogen cyanide
F. mercury
G. toxic trace metals (lead, cadmium, and arsenic)
H. nitric oxides (NO and NO_2)
I. tobacco specific nitrosamines (N-nitrosonornicotine (NNN), 4-(N-nitrosomethylamino)- 1-(3-pyridyl)-1 butanone (NNK), N-nitrosoanatabine (NAT) and N-nitrosoanabasine (NAB))
J. selected basic semi-volatiles (pyridine and quinoline)
K. phenolic compounds (hydroquinone, catechol, phenol, m+p-cresol, and o-cresol)
L. tar and carbon monoxide
M. selected volatiles (1, 3-butadiene, isoprene, acrylonitrile, benzene, toluene, styrene)

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665.300: Smoke Constituent Reporting Form

Brand Name: _____

Sub Brand: _____

constituent		Massachusetts Smoke Constituent Yields					
		Mainstream Smoke			Sidestream Smoke		
		Mean	Std Dev	C.V.	Mean	Std Dev	C.V.
Nicotine	mg/cig						
"Tar"	mg/cig						
CO	mg/cig						
Ammonia	µg/cig						
2-Aminonaphthalene	ng/cig						
1-Aminonaphthalene	ng/cig						
4-Aminobiphenyl	ng/cig						
3-Aminobiphenyl	ng/cig						
Benzo(a)pyrene	ng/cig						
Formaldehyde	µg/cig						
Acetaldehyde	µg/cig						
Acetone	µg/cig						
Acrolein	µg/cig						
Propionaldehyde	µg/cig						
Crotonaldehyde	µg/cig						
Methyl Ethyl Ketone	µg/cig						
Butyraldehyde	µg/cig						
Hydrogen Cyanide	µg/cig						
Mercury	ng/cig						
Lead	ng/cig						
Cadmium	ng/cig						
Arsenic	ng/cig						
Nitric Oxide	µg/cig						
Nitrogen Dioxide	µg/cig						
Nitrosonornicotine (NNN)	ng/cig						
4-(N-nitrosomethylamino) -1-(3-pyridyl)-1-butanone (NNK)	ng/cig						
Nitrosoanatabine (NAT)	ng/cig						
Nitrosoanabasine (NAB)	ng/cig						
Pyridine	µg/cig						
Quinoline	µg/cig						
Hydroquinone	µg/cig						
Catechol	µg/cig						
Phenol	µg/cig						
m- + p-Cresol	µg/cig						
o-Cresol	µg/cig						
1,3-Butadiene	µg/cig						
Isoprene	µg/cig						
Acrylonitrile	µg/cig						
Benzene	µg/cig						
Toluene	µg/cig						
Styrene	µg/cig						

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